

APPENDIX U

**Chart demonstrating that all of Claims 1-91 of the '468 patent
correspond to the Count**

Claim of Collins U.S. Patent No. 6,110,468	Why Collins claim corresponds to the Count
<p>1. A vaccine comprising attenuated swine infertility and respiratory syndrome virus, wherein said attenuated swine infertility and respiratory syndrome virus is produced by a process comprising passaging a swine infertility and respiratory syndrome virus through simian cells to form an attenuated swine infertility and respiratory syndrome virus which is non-zoopathogenic in swine; and</p> <p>the swine infertility and respiratory syndrome virus is a fastidious, non-hemagglutinating, enveloped RNA virus.</p>	<p>Claim 12, which is one alternative of the Count, specifies that the vaccine comprises attenuated swine infertility and respiratory syndrome virus, wherein said attenuated swine infertility and respiratory syndrome virus is produced by a process comprising passaging a swine infertility and respiratory syndrome virus through simian cells to form a swine infertility and respiratory syndrome virus which is non-zoopathogenic in swine.</p> <p>The '468 patent states that "the North American and European [Lelystad agent] diseases are caused by the same virus, a fastidious, non-hemagglutinating enveloped RNA virus" ('468 patent at Col. 9, ll. 1-6); the Lelystad agent was known at the time of filing the earliest Collins application. (Vet Q. 1991 Jul;13(3):121-30).</p> <p>As such, Claim 12 anticipates Claim 1, and Claim 1 therefore corresponds to the Count.</p>
<p>2. The vaccine of claim 1 wherein the simian cells are simian kidney cells.</p>	<p>Claim 12 specifies that the simian cells are simian kidney cells. As such, Claim 12 anticipates Claim 2, and Claim 2 therefore corresponds to the Count.</p>
<p>3. The vaccine of claim 2 wherein the simian kidney cells are MA-104 simian kidney cells.</p>	<p>Claim 12 specifies that the simian kidney cells are MA-104 cells. As such, Claim 12 anticipates Claim 3, and Claim 3 therefore corresponds to the Count.</p>
<p>4. The vaccine of claim 1 wherein the swine infertility and respiratory syndrome virus is purified by gradient or serial cell culturation.</p>	<p>Claim 12 specifies that the virus is purified by passaging in cells. As such, Claim 12 anticipates Claim 4, and Claim 4 therefore corresponds to the Count.</p>

5. The vaccine of claim 1 wherein the swine infertility and respiratory syndrome virus is swine infertility and respiratory syndrome virus ATCC VA [sci, VR]-2332.	Claim 12 specifies that the virus is ATCC VR-2332. As such, Claim 12 anticipates Claim 5, and Claim 5 therefore corresponds to the Count.
6. The vaccine of claim 1 having a titer of the attenuated swine infertility and respiratory syndrome virus of 10^3 to 10^7 TCID ₅₀ /ml.	Claim 6 depends from Claim 1, which is anticipated by Claim 12, and merely additionally states that the vaccine has a titer of 10^3 to 10^7 TCID ₅₀ /ml. It was routine in the art to make a vaccine with a titer of virus of 10^3 to 10^7 TCID ₅₀ /ml. (cite) As such, Claim 6 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.
7. The vaccine of claim 1 wherein passaging the swine infertility and respiratory syndrome virus through the simian cells comprises incubating simian cells inoculated with the swine infertility and respiratory syndrome virus in a growth medium which includes serum.	Claim 7 depends from Claim 1, which is anticipated by Claim 12, and merely additionally states that the growth medium includes serum. It was routine in the art to grow virus in a culture of cells wherein the growth medium includes serum. (cite) As such, Claim 7 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.
8. The vaccine of claim 7 wherein the serum includes fetal calf serum.	Claim 8 depends from Claim 7, which depends from Claim 1, which is anticipated by Claim 12, and merely additionally states that the growth medium includes fetal calf serum. It was routine in the art to grow virus in a culture of cells wherein the growth medium includes fetal calf serum. (cite) As such, Claim 8 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.
9. The vaccine of claim 7 comprising incubating the inoculated simian cells at about 34° C. to 37° C. until a cytopathic effect is observed.	Claim 9 depends from Claim 7, which depends from Claim 1, which is anticipated by Claim 12, and merely additionally states that the inoculated cells are incubated at about 34° C to 37° C until a cytopathic effect is observed. It was routine in the art to incubate inoculated cells at about 34° C to 37° C until a cytopathic effect is observed. (cite) As such, Claim 9 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.

10. A method of immunizing swine against swine infertility and respiratory syndrome comprising administering the vaccine of claim 1 to swine.	Claim 10 depends from Claim 1, which is anticipated by Claim 12, and merely additionally states that the vaccine is administered to swine. It would have been obvious to administer a vaccine comprising a swine virus to a swine. As such, Claim 10 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.
11. A vaccine suitable for use in prevention of swine infertility and respiratory syndrome, comprising: (a) attenuated swine infertility and respiratory syndrome virus; and (b) pharmaceutical carrier; wherein the attenuated swine infertility and respiratory syndrome virus produced by a process comprising passaging swine infertility and respiratory syndrome virus ATCC VR-2332 through simian cells to form modified swine infertility and respiratory syndrome virus which is non-zoopathogenic in swine.	Claim 12 is one alternative of the Count, and is dependent on Claim 11. As such, Claim 12 contains all the limitations of Claim 11, and therefore anticipates Claim 11.
12. The vaccine of claim 11 wherein the simian cells are MA-104 simian kidney cells.	Claim 12 is one alternative of the Count.
13. The vaccine of claim 11 having a titer of the attenuated swine infertility and respiratory syndrome virus of 10^3 to 10^7 TCID ₅₀ /ml..	Claim 13 depends from Claim 11, which is anticipated by Claim 12, one alternative of the Count. It was routine in the art to make a vaccine with a titer of virus of 10^3 to 10^7 TCID ₅₀ /ml.. (cite) As such, Claim 13 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.
14. A method of immunizing swine against swine infertility and respiratory syndrome comprising administering the vaccine of claim 13 to swine.	Claim 14 depends from Claim 13, which is obvious over Claim 12, one alternative of the Count. It would have been obvious to administer a vaccine comprising a swine virus to a swine. As such, Claim 14 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.

<p>15. A vaccine comprising attenuated swine infertility and respiratory syndrome virus, wherein said attenuated swine infertility and respiratory syndrome virus is produced by a process comprising:</p> <p>homogenizing tissue from swine affected with swine infertility and respiratory syndrome to form a homogenate which includes swine infertility and respiratory syndrome virus, wherein the swine infertility and respiratory syndrome virus is a fastidious, non-hemagglutinating, enveloped RNA virus; and</p> <p>passaging the swine infertility and respiratory syndrome virus through simian cells to form an attenuated swine infertility and respiratory syndrome virus which is non-zoopathogenic in swine, wherein the passaging step comprises incubating simian cells inoculated with material from the homogenate.</p>	<p>Claim 12, which is one alternative of the Count, specifies that the vaccine comprises attenuated swine infertility and respiratory syndrome virus, wherein said attenuated swine infertility and respiratory syndrome virus is produced by a process comprising passaging a swine infertility and respiratory syndrome virus through simian cells to form a swine infertility and respiratory syndrome virus which is non-zoopathogenic in swine.</p> <p>Claim 15 merely additionally specifies that the virus is obtained by homogenizing tissue from an affected animal. It was routine to isolate virus by homogenizing tissue from an animal affected with a disease in order to obtain the virus causing the disease. (cite) As such, Claim 15 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.</p>
<p>16. The vaccine of claim 15 wherein the homogenate is a filtered homogenate.</p>	<p>Claim 16 is dependent from Claim 15, which is obvious over the Count, and merely additionally specifies that the homogenate is filtered. It was routine to filter a homogenate. (cite) As such, Claim 16 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.</p>
<p>17. The vaccine of claim 16 wherein the homogenate contains biological particles having a size of no greater than about 0.1 micron.</p>	<p>Claim 17 is dependent from Claim 16, which is obvious over the Count, and merely additionally specifies that the homogenate contains biological particles having a size of no greater than about 0.1 micron. It would have been expected to obtain biological particles having a size of no greater than about 0.1 micron. (cite) As such, Claim 17 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.</p>

18. The vaccine of claim 15 wherein the homogenate is purified by neutralization with antibody sera to swine diseases selected from the group consisting of hemophilus, brucellosis, leptospira, parvovirus, pseudorabies, encephalomyocarditis, enterovirus, swine influenza and any combination thereof.	Claim 18 is dependent from Claim 15, which is obvious over the Count, and merely additionally specifies that the homogenate is purified by neutralization with antibody sera to swine diseases. It was known to purify a virus homogenate by neutralization with antibody sera to other diseases known to occur in the animal. (cite) As such, Claim 18 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.
19. The vaccine of claim 15 wherein the homogenate comprises lung tissue.	Claim 19 is dependent from Claim 15, which is obvious over the Count, and merely additionally specifies that the homogenate comprises lung tissue. It would have been obvious to isolate a virus causing a respiratory disease from lung tissue. As such, Claim 19 is obvious over Claim 12, one alternative of the Count, and therefore corresponds to the Count.